REMARKS/ARGUMENTS

Reconsideration and entry of this Amendment are requested. Claims 35-39 and 41-43 will be active in the application subsequent to entry of this Amendment.

It is proposed to incorporate the subject matter of claim 40 into independent claim 35 while making minor adjustments to claims 36, 38 and 41.

In the Official Action claims 35-39 and 41-43 were rejected as being anticipated by U.S. patent 5,716,615. While applicant disagrees with the examiner's position and statements in support of the anticipation rejection, in order to advance prosecution the subject matter of claim 40 is incorporated into claim 35, thus this rejection is moot.

Claim 41 is amended to refer to enzymatically active extracts as described in the specification at page 4, lines 12-13.

All of the previous claims were rejected under 35 USC §103(a) as being unpatentable over a combination of U.S. 5,716,615 taken with WO 98/22082 and Sjokvist et al. This rejection is respectfully traversed to the extent that it may pertain to the amended claims presented above.

The rejection is flawed in many aspects primarily in the fact that the main reference relates to **certain** gastrointestinal disorders (See Summary of the Invention); the specific disclosure is directed only to specific disorders, which have already been excluded from applicant's claims. Indeed, the reference mentions diarrhea, constipation, hypercholesterolemia, endotoxin absorption or production of endogenous toxic substances (Summary of the Invention) yet specific disclosure is given for chronic hepatitis following C virus infection, for treating the following symptoms: anorexia, itching, nausea, diarrhea, constipation and insomnia (only the underlined ones can be considered gastrointestinal disturbances), as per Example 1; high cholesterol levels (Example 2) and irritable bowel syndrome (Example 3). The specific disclosures of this document are not reasonably suggestive of the procedures defined by claim 35 as above amended.

On page 6 of the Official Action in responding to applicant's earlier comments, the examiner observes "The treatment of disorders as claimed is an intended effect" which, of course, is true of any method of treatment claim – the objective of the procedure is not to ingest a particular product, the objective is to secure a beneficial result. Accordingly, the "intended effect" is the subject of concern and the area for consideration, the procedures and means to attain the desired result are of secondary importance. Thus while it is argued that "the patient and the drug are identical" (this is no longer true) and "the identical one active step method as presently claimed" is disclosed in the prior art, it is the objective of the procedure that lies at the heart of the invention, not necessarily the means to attain that feature. The Official Action fails to take these important considerations into account when interpreting and applying U.S. 5,716,615.

In addition, U.S. 5,716,615 discloses the treatment of certain gastrointestinal diseases, which are different from the claimed ones, by administering lactic acid bacteria. To be effective, the bacteria must be at concentration of at least 10^{11} live bacteria/gram of composition and there is no suggestion that the therapeutic effect is due to alkaline sphingomyelinase. The present invention employs a new strain possessing alkaline sphingomyelinase activity. The use according to the present invention of bacteria endowed with this specific enzyme activity allows one to administer even far lower concentrations of lactic acid bacteria (down to 1×10^2) than the ones provided by U.S. 5,716,615.

The Official Action at page 2, last paragraph, and again on page 3, second full paragraph, discusses "effective amounts" in terms of concentration of lactic acid bacteria. In fact the reference teaches that, in order to obtain therapeutic effects, the concentration of the lactic acid bacteria must be above 10^{11}/gram of composition. The present invention, by using only alkaline sphingomyelinase-producing lactic acid bacteria, allows using also far lower concentrations, i.e. starting from 1×10^2/gram of composition to attain the result desired.

Necessarily, reliance is placed upon two secondary references in order to support the rejection of the claims. As applicants have previously explained, WO 98/22082 is not applicable to the claimed invention, since this reference deals only with neutral sphingomyelinase, whereas the present invention deals only with alkaline sphingomyelinase. The former applies to the dermatological field, the latter to gastrointestinal field. See the cited reference, page 3, Results, where only neutral sphingomyelinase was detected. The examiner will also note claim 35 features oral or parenteral administration, not topical as would be customary in the dermatological field. This reference bears no relationship to the claims now under consideration.

Applicants have also previously addressed in some detail the non-pertinence of Sjokvist and have indeed amended their claims to refer to acute inflammatory intestinal diseases which is not related to the chronic diseases discussed in this reference.

In summary, the teachings of the references when combined is not suggestive of the subject matter defined by applicants' claims as above amended.

Reconsideration, entry of this Amendment and favorable Action are solicited.

Respectfully submitted,

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